Clinical Policy: Tesamorelin (Egrifta)

Reference Number: PA.CP.PHAR.109
Effective Date: 01/2018
Last Review Date: 07/2022 Revision Log

Description
Tesamorelin (Egrifta SV™) is a growth hormone releasing factor analog.

FDA Approved Indication(s)
Egrifta SV is indicated for the reduction of excess abdominal fat in human immunodeficiency virus (HIV)-infected patients with lipodystrophy.

Limitation(s) of use:
- Since the long-term cardiovascular safety and potential long-term cardiovascular benefit of Egrifta SV treatment have not been studied and are not known, careful consideration should be given whether to continue Egrifta SV treatment in patients who do not show a clear efficacy response as judged by the degree of reduction in visceral adipose tissue measured by waist circumference or CT scan.
- Egrifta SV is not indicated for weight loss management (weight neutral effect).
- There are no data to support improved compliance with anti-retroviral therapies in HIV-positive patients taking Egrifta SV.

Policy/Criteria
It is the policy of PA Health & Wellness that Egrifta SV® is **medically necessary** when one of the following criteria are met:

I. Initial Approval Criteria

A. Human immunodeficiency virus (HIV) with Lipodystrophy (must meet all):
1. Diagnosis of HIV infection with lipodystropy;
2. Age ≥ 18 years or documentation of closed epiphyses;
3. Meets clinical indicators for abdominal lipodystrophy (a or b):
   a. If female, waist circumference ≥ 88 cm;
   b. If male, waist circumference ≥ 102cm;
4. Member is currently receiving and adherent to antiretroviral therapy;
5. Prescribed dose of Egrifta SV does not exceed 1.4 mg once daily.

Approval Duration: 6 months

B. Other diagnoses/indications : Refer to PA.CP.PMN.53

II. Continued Approval

A. HIV with Lipodystrophy (must meet all)**:**
1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;

3. If request is for a dose increase, new dose does not exceed 1.4 mg per day.

Approval Duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
HIV: human immunodeficiency virus

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Disruption of the hypothalamic-pituitary axis due to hypophysectomy, hypopituitarism, pituitary tumor/surgery, head irradiation or head trauma
  - Active malignancy (either newly diagnosed or recurrent): any preexisting malignancy should be inactive and its treatment complete prior to instituting therapy with Egrifta SV
  - Pregnancy: During pregnancy, visceral adipose tissue increases due to normal metabolic and hormonal changes. Modifying this physiologic change of pregnancy with Egrifta SV offers no known benefit and could result in fetal harm. If pregnancy occurs, discontinue Egrifta SV therapy
  - Known hypersensitivity to tesamorelin and/or mannitol
- Boxed warning(s): none reported

Appendix D: General Information

- On June 15, 2020, Theratechnologies discontinued Egrifta and permanently replaced it with Egrifta SV, a smaller volume injection able to be stored at room temperature.

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
HIV infection with lipodystrophy	1.4 mg (0.35 mL) SC QD After reconstitution and administration, any unused solution should be thrown away	1.4 mg/day

V. Product Availability

Single-use vial with powder for reconstitution: 2 mg

VI. References

1. Egrifta SV Prescribing Information. Montreal, Quebec, Canada: Theratechnologies Inc.; October 2019. Available at http://www.egriftasv.com. Accessed March 29, 2022.
2. Lean ME, Han TS, Morrison CE. Waist circumference as a measure for indicating need for weight management. BMJ 1995; 311:158.

HCPCS Codes	Description
J3590	Unclassified biologics
J3490	Unclassified drugs

Reviews, Revisions, and Approvals	Date	Approval Date
Removed adherence to current antiretroviral therapy on re-auth; pregnancy contraindication added per safety guidance endorsed by Centene Medical Affairs; references reviewed and updated.	05/2018	
3Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	07/2019	
3Q 2020 annual review: replaced old formulation Egrifta with new formulation Egrifta SV and updated dose; removed pregnancy contraindication from criteria as separate edits are in place to address these risks; references reviewed and updated.	07/2020	
3Q 2021 annual review: no significant changes; references reviewed and updated.	07/2021	
3Q 2022 annual review: no significant changes; added quantity restriction (1 vial per day) to dosing requirement; updated HCPCS codes; references reviewed and updated.	07/2022	